

Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

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In the Case of:)	DATE: August 26, 2008
)	
Dialysis Center at Moreno)	
Valley, Inc.,)	
)	
Petitioner,)	Civil Remedies CR1733
)	App. Div. Docket No. A-08-75
)	
- v. -)	Decision No. 2193
)	
Centers for Medicare &)	
Medicaid Services.)	
_____)	

FINAL DECISION ON REVIEW OF
ADMINISTRATIVE LAW JUDGE DECISION

Dialysis Center at Moreno Valley, Inc. (Moreno Valley) appealed the February 6, 2008 decision by Administrative Law Judge (ALJ) Steven T. Kessel. Dialysis Center at Moreno Valley, Inc., DAB No. CR1733 (2008) (ALJ Decision). The ALJ Decision granted summary judgment in favor of the Centers for Medicare & Medicaid Services (CMS), sustaining CMS's determination to terminate Medicare coverage for the services furnished by Moreno Valley effective at the close of business on August 31, 2007.

For the reasons discussed below, we uphold the ALJ Decision. As explained in detail below, as a preliminary matter, we admit several exhibits proffered by Moreno Valley into the record for the limited purpose of evaluating whether summary judgment is appropriate. We then affirm the ALJ's legal conclusion that summary judgment may be entered in an appeal brought under 42 C.F.R. Part 498 where there are no disputed issues of material fact.

Next, we uphold the finding that undisputed material facts establish that Moreno Valley did not meet the condition for coverage at 42 C.F.R. § 405.2140 (physical environment). We explain that Moreno Valley raised several issues of fact relating to the physical environment requirements. The facility's factual allegations, however, even if true, would not affect the outcome of the appeal since the undisputed survey findings independently establish that the facility failed to meet the physical environment condition. Viewing the record in the light most favorable to the facility, a rational trier of fact could not conclude that Moreno Valley met the physical environment condition.

Finally, we uphold the ALJ's conclusion that CMS's termination action must be affirmed based on the facility's failure to meet the physical environment condition and the mandatory language of 42 C.F.R. § 405.2180.

Legal Background

Under section 1881 of the Social Security Act,¹ Medicare pays for covered services furnished to beneficiaries with end-stage renal disease (ESRD). Section 1881(b)(1) of the Act and the regulations at 42 C.F.R. Part 405, subpart U,² set forth the requirements that ESRD suppliers, including renal dialysis facilities,³ must meet to be certified and receive Medicare payments. The regulations include both conditions and standards for certification. Each condition represents a general requirement, and the standards represent the components of the conditions.

¹The current version of the Social Security Act can be found at www.ssa.gov/OP_Home/ssact/comp-ssa.htm. Each section of the Act on that website contains a reference to the corresponding United States Code chapter and section. Also, a cross reference table for the Act and the United States Code can be found at 42 U.S.C.A. Ch. 7, Disp Table.

²The regulatory citations in this decision refer to the rules in effect in 2007.

³ Section 405.2102(c) of 42 C.F.R. defines a "renal dialysis facility" as "[a] unit which is approved to furnish dialysis service(s) directly to ESRD patients."

The introductory, or lead-in, language of the condition at 42 C.F.R. § 405.2140 provides:

The physical environment in which ESRD services are furnished affords a functional, sanitary, safe, and comfortable setting for patients, staff, and the public.

The regulation then sets forth detailed requirements under four standards, which address: building and equipment (42 C.F.R. § 405.2140(a)); favorable environment for patients (42 C.F.R. § 405.2140(b)); standard contamination prevention (42 C.F.R. § 405.2140(c)); and emergency preparedness (42 C.F.R. § 405.2140(d)).

ESRD suppliers are subject to the survey, certification, and enforcement procedures at 42 C.F.R. Part 488. Under 42 C.F.R. §§ 488.10-12, state agencies under agreement with CMS conduct surveys and make recommendations regarding whether ESRD suppliers meet the applicable conditions and standards. Under 42 C.F.R. § 488.24(b), a state agency "will certify that . . . a supplier is not or is no longer in compliance with the conditions . . . for coverage where the deficiencies are of such character as to substantially limit the . . . supplier's capacity to furnish adequate care or which adversely affect the health and safety of patients." With one type of exception, not relevant here as discussed below, the failure of an ESRD facility to meet one or more of the conditions set forth in subpart U "will result in termination of Medicare coverage of the services furnished by that supplier." 42 C.F.R. § 405.2180(a).

An ESRD supplier dissatisfied with a CMS determination to terminate coverage of services furnished by the supplier for failure to meet a condition for coverage may request an ALJ hearing pursuant to the regulations at 42 C.F.R. Part 498. 42 C.F.R. § 405.2182(b).

Background

The following undisputed facts are drawn from the ALJ Decision and the record below.

Moreno Valley is a supplier of dialysis services. On March 5, 2007, the California Department of Public Health (State agency) completed a Medicare compliance survey of Moreno Valley. By letter dated April 12, 2007, CMS notified Moreno Valley that the survey documented that the facility was not in substantial compliance with the ESRD conditions for coverage.

On July 16, 2007, the State agency completed a revisit survey of Moreno Valley to determine whether the facility had corrected the deficiencies cited in the March survey. The State agency determined that Moreno Valley continued to be noncompliant with the conditions for coverage. Specifically, the July survey statement of deficiencies (SOD) cited numerous findings to support the conclusion that Moreno Valley did not meet the following three conditions: 1) 42 C.F.R. § 405.2136, Governing body and management; 2) 42 C.F.R. § 405.2140, Physical environment; and 3) 42 C.F.R. § 405.2161, Director of a renal dialysis facility.

Based on the survey findings, CMS issued a determination on August 7, 2007 that "[t]here will be no payment for services rendered to Medicare/Medicaid beneficiaries admitted for treatment after August 31, 2007." CMS Notice of Termination, August 7, 2007, at 2. CMS concluded that the deficiencies documented in the SOD "either individually or in combination substantially limit[ed] the ESRD [facility's] capacity to render adequate care or adversely affect[e]d patient health and safety, thus establishing a basis under 42 C.F.R. § 405.2180 for concluding that the above-referenced Conditions for Coverage were not met." *Id.* CMS additionally stated that the July 16, 2007 resurvey documented that Moreno Valley had failed to correct numerous deficiencies identified in the SOD for the March 5, 2007 survey.

Moreno Valley timely requested a hearing before an ALJ to contest CMS's determination. The ALJ granted CMS's motion for summary judgment against Moreno Valley in his decision dated February 6, 2008.

The ALJ Decision

The ALJ first concluded that "summary judgment is appropriate where there are no disputed issues of material fact." ALJ Decision at 3 (finding of fact and conclusion of law (FFCL) 1). The ALJ noted that the regulations at 42 C.F.R. Part 498 do not expressly provide for summary judgment to be entered in appeals brought under that part. The ALJ stated that the regulations have, however, been interpreted to permit summary judgment in Part 498 appeals "in circumstances that are analogous to those for which summary judgment is appropriate under Rule 56 of the Federal Rules of Civil Procedure." *Id.*

Applying the standards of Rule 56, the ALJ determined, summary judgment was appropriate since undisputed material facts alleged by CMS supported a finding that Moreno Valley failed to comply

with the physical environment condition at 42 C.F.R. § 405.2140. ALJ Decision at 3 (FFCL 2). The ALJ concluded that the material facts alleged by CMS (based on the findings in the SOD) to show that Moreno Valley failed to comply with section 405.2140, "if supported at a hearing, would be prima facie proof" that Moreno Valley was not in compliance with the condition. Id. at 4.

Next, the ALJ determined, Moreno Valley failed to offer evidence or arguments to create a genuine dispute of material fact with respect to CMS's allegations of noncompliance with the physical environment condition. Id. at 4-5. The ALJ stated that Moreno Valley's reply to CMS's motion for summary judgment did "assert[] facts which, if proven, might support a finding that it had in fact complied with some, but not all, of the elements of the conditions stated at 42 C.F.R. §§ 405.2136 and 405.2161." Id. at 3-4. "However," the ALJ determined, Moreno Valley "failed to offer facts and argument to refute CMS's allegations of noncompliance with the requirements of 42 C.F.R. § 405.2140." Id. at 4. The ALJ further found that while "scattered statements" in Moreno Valley's hearing request could be read as relating to CMS's allegations of noncompliance with the physical environment condition, the facility's statements did not "squarely refute" the allegations. Id. at 5.

The ALJ additionally rejected Moreno Valley's contention that the survey findings and termination decision were the result of a "vendetta" waged against the facility by employees of the State agency. The ALJ found that Moreno Valley "offered no facts to show how any animus displayed towards [Moreno Valley], if indeed there was animus, affected the findings of noncompliance that were made ultimately by CMS." Id. at 6.

Finally, the ALJ concluded that "CMS's determination to terminate [Moreno Valley's] participation in Medicare as an ESRD supplier [was] authorized by [Moreno Valley's] failure to comply with a condition of participation," pursuant to 42 C.F.R. § 405.2180. ALJ Decision at 6-7 (FFCL 3). The ALJ further stated that, since summary judgment was appropriate with respect to Moreno Valley's failure to comply with the condition governing physical environment, he need not address the allegations of noncompliance involving the conditions at 42 C.F.R. §§ 405.2136 and 405.2161.

Standard of Review

Whether to enter summary judgment is a legal issue that the Board addresses de novo. Lebanon Nursing and Rehabilitation Center, DAB No. 1918 (2004).

Admission of New Evidence

Moreno Valley, which is represented pro se by its President, submitted to the Board with its reply brief various unlabelled documents that were not a part of the record of the ALJ proceedings. CMS chose not to respond to Moreno Valley's proffer of new evidence.

The procedural regulations at 42 C.F.R. § 498.86 permit the Board to admit new evidence that is relevant and material, after following certain procedures. Board Guidelines provide that the Board will admit the proffered evidence only if it considers the additional evidence to be relevant and material to an issue before it. See Appellate Review of Decisions of Administrative Law Judges Affecting a Provider's Participation in the Medicare and Medicaid Programs, <http://www.hhs.gov/dab/guidelines/prov.html>. The Board also considers whether the party that proffered the evidence has demonstrated good cause for not producing the evidence during the proceedings before the ALJ.

In other circumstances, we might decline to admit these documents into the record. Mindful that the facility's representative is not an attorney, however, we conclude that it is appropriate to consider Moreno Valley's proffer of new evidence for the limited purpose of determining whether summary judgment is appropriate.

Accordingly, we admit the documents submitted by Moreno Valley into the record as follows: Reverse osmosis maintenance logs, Petitioner (P.) Ex. 1; Laboratory microbiology and water analysis reports, P. Ex 2; Patient care procedures for infection control and isolation technique - Hepatitis B, P. Ex. 3; and signed patient instructions on emergency evacuation procedures (including "clamp and cut" procedures) and signed acknowledgments of receipt of such instructions, P. Ex. 4. We discuss these exhibits in our analysis below.

Analysis

1. Summary judgment is appropriate where there are no disputed issues of material fact. FFCL 1.

We affirm the ALJ's conclusion as to the proper standard for evaluating whether summary judgment is appropriate in an appeal brought under 42 C.F.R. Part 498. As the ALJ observed, the regulations do not include standards to determine when summary judgment may be entered. The Board and federal courts have, however, upheld procedures that allow ALJs to enter summary judgment without an oral hearing in certain circumstances. See, e.g., Crestview Parke Care Ctr. v. Thompson, 373 F.3d 743 (6th Cir. 2004). Some ALJs, including the ALJ in this matter, have notified parties that they will apply Rule 56 of the Federal Rules of Civil Procedure. Acknowledgment and Initial Pre-hearing Order, October 25, 2007, at 4. Further, the Board has developed a framework for analyzing when summary judgment without an oral hearing may be entered in an appeal brought under Part 498. See, e.g., Lebanon; Madison Health Care, Inc., DAB No. 1927 (2004). That framework is drawn from the standards established under Rule 56, federal case law, and consideration of the nature and purpose of the administrative proceedings. Vandalia Park, DAB No. 1939 (2004).

Summary judgment is appropriate if there are no disputes of fact material to the outcome of the case. Lebanon at 3-4, citing Celotex Corp. v. Catrett, 477 U.S. 317, 322-25 (1986); Matsushita Elec. Industrial Co. v. Zenith Radio, 475 U.S. 574, 587 (1986). The moving party must show that it is entitled to judgment as a matter of law and that no genuine issues of material fact remain, which it may do by showing that no evidence in the record supports a judgment for the non-moving party. Celotex at 322-323, 325. To defeat an adequately supported motion for summary judgment, the non-moving party may not rely on mere denials in its pleadings or briefs, but must furnish evidence of a dispute concerning a *material* fact -- a fact that, if proven, would affect the outcome of the case. Matsushita at 586, n.11; Celotex, 477 U.S. at 322. In evaluating a motion for summary judgment, an adjudicator may not make credibility determinations or weigh conflicting evidence, but must instead view the entire record in the light most favorable to the non-moving party, drawing all reasonable inferences from the evidence in that party's favor. Madison Health Care, Inc. at 6, citing Payne v. Pauley, 337 F.3d 767, 770 (7th Cir., 2003).

Consequently, if CMS has made a prima facie showing that a facility failed to meet a condition for coverage -

based on either uncontested facts, or on a combination of uncontested facts and evidence concerning contested facts - the facility can avoid summary judgment only if it proffers competent evidence of a genuine . . . dispute [of material fact] or demonstrates that the record, viewed in the light most favorable to the facility, might lead a rational trier of fact to conclude that the facility was in substantial compliance.

Guardian Health Care Center, DAB No. 1943, at 9 (2004), citing Lebanon at 5. "Ultimately, if the proffered evidence as a whole, viewed in the light most favorable to the facility, might cause a rational trier of fact to reach an outcome in favor of the facility, summary judgment . . . is not appropriate." Lebanon at 5. If, however, the facility either has conceded all of the material facts or proffered evidence only on facts which, even if proved, clearly would not make any substantive difference in the result, summary disposition is appropriate. Big Bend Hospital Corp., DAB No. 1814 (2002), aff'd, Big Bend Hospital Corp. v. Thompson, No. P-02-CA-030 (W.D. Tex. Jan. 2, 2003).

When evaluating whether to enter summary judgment, an ALJ may rely on the factual findings in a survey SOD that are not placed in dispute by the facility. St. Catherine's Care Center of Findlay, Inc., DAB No. 1964, at 8-9 (2005). The SOD, the Board has held, "is a contemporaneous record of the survey agency's observations and investigative findings, and . . . CMS may make a prima facie showing of noncompliance based on that document if the factual findings and allegations it contains are specific, undisputed, and not inherently unreliable." Guardian at 14, citing Glenburn Home, DAB No. 1806, at 25 (2002). Thus, the SOD may constitute evidence on specific disputed facts as to which, if material, the facility must proffer sufficient evidence to show a genuine dispute in order to defeat CMS's motion for summary judgment. St. Catherine's Care Center of Findlay at 9.

2. Undisputed material facts support the conclusion that Moreno Valley did not meet the physical environment condition for coverage at 42 C.F.R. § 405.2140. FFCL 2.

Applying the analytic framework described above to the record in this case, we conclude that summary judgment against Moreno Valley for failure to meet the physical environment condition at

section 405.2140 is appropriate. First, we summarize the findings in the SOD on which CMS relied to demonstrate the facility's noncompliance with the condition. We next describe Moreno Valley's submissions both below and on appeal. Analyzing the facility's submissions, we find that several of Moreno Valley's allegations could be construed as raising relevant factual issues. We further explain, however, that the issues of fact disputed by Moreno Valley are immaterial since they do not affect the outcome of the appeal; the survey findings that the facility did not contest are sufficient to establish that the facility failed to meet the physical environment requirements at the condition level.

A. The factual findings in the SOD

The SOD from the July 2007 survey set forth an extensive and detailed series of findings, based on surveyor observations, document review and interviews. With respect to the physical environment condition at 42 C.F.R. § 405.2140, the SOD alleged that Moreno Valley failed to meet the following three standards: building and equipment (42 C.F.R. § 405.2140(a)); favorable environment for patients (42 C.F.R. § 405.2140(b)); and emergency preparedness (42 C.F.R. § 405.2140(d)). We describe below the findings alleged in the SOD under each standard.

42 C.F.R. § 405.2140(a)

The lead-in language of the building and equipment standard at section 405.2140(a) requires the "physical structure in which ESRD services are furnished [to be] constructed, equipped, and maintained to insure the safety of patients, staff, and the public." The SOD stated that the facility's noncompliance with this requirement posed "immediate jeopardy" to Moreno Valley's patients. CMS Ex. 1, at 36, 38. Under the regulation at 42 C.F.R. § 489.3, immediate jeopardy means that the noncompliance had "caused, or [was] likely to cause, serious injury, harm, impairment, or death." In this case, the SOD stated that immediate jeopardy was due to Moreno Valley's failure --

. . . to ensure that the drainage system, in which used dialysate (the solution that carries the waste products removed from the dialysis patient's blood) drains from the patients, was constructed and maintained to prevent back-up and overflow of the used dialysate solution[,] which caused mold and water damage [that] had the potential for causing fungal infections and respiratory problems. The facility also failed

to ensure that a product water hose (a hose that carries pretreated water to dialysis stations) was intact and not leaking.

CMS Ex. 1, at 38. The SOD documented two groups of findings which support this conclusion.

The first group of findings was based on the surveyor's observations that: the baseboards behind several hemodialysis stations "were heavily stained with a brownish substance;" the wood and laminate at the drain area behind one of the dialysis stations was "buckling and lifting;" there were "water stain[s] underneath several sinks" and "lifting laminate on the counter area" of one sink; inside the cabinet immediately behind another dialysis machine and patient chair there were "large areas of brownish black staining with a brown build-up noted on the floor [and] the majority of the staining appeared to be coming from the drain tubing and pipes in which used dialysate . . . drains;" a drain pipe coming from one dialysis station "was 'Y'ed into the main drainage system with the 'Y' connecting pipe facing the wrong direction . . . causing the drainage to go against the normal drain flow;" in another cabinet "the laminate and wood around the dialysate drain tubing was also lifted and buckled;" "there were multiple dialysate drainage pipes opening into an open drain," and "the entire drain and the surrounding area had a build up of brownish rust colored material, which went throughout the bottom of the cabinet." Id. at 39-40.

The SOD also stated that behind two dialysis stations there were "black and white colored stains that appeared to be mold on the wallboard, framing boards, and bottom of the cabinets, [and] [t]he area appeared to be wet." Id. at 40. The surveyor further documented "multiple areas in which the drainage pipes were placed in a manner that would require the drainage to travel in an uphill manner, which posed the risk of the solution to back-up or stagnate in the drainage pipes." In addition, the SOD stated that "the facility did not have a schematic layout of the drainage system." Id.

The SOD concluded with respect to the first group of findings that "[t]he mold and water damage had the potential for causing fungal infections and respiratory problems especially within the dialysis patients" due to the likelihood of the patients' "decreased immunity to infections." Id.

In the second group of findings relating to Moreno Valley's alleged noncompliance with the general requirement of section 405.2140(a), the SOD stated that "the product water (the water used to perform dialysis) spout behind [one] dialysis station . . . was leaking and the wallboard was warping and the baseboard was stained." Id. at 41. The SOD noted that "a portion of the tubing that was leaking was wrapped with paper tape that is used for taping bandages . . . [which] is not waterproof and did not stop the leaking of the product water." Id.

42 C.F.R. § 405.2140(a)(1)

The building and equipment standard requirement at subsection 405.2140(a)(1) provides that ". . . [f]ire regulations and fire management procedures [must be] prominently posted and properly followed." According to the surveyor's observations and interviews recorded in the SOD, Moreno Valley's evacuation plans were not prominently posted and were difficult to see and understand. The SOD documented that the plans were in eight-by-ten inch frames, of poor quality, and hung on walls behind or near dialysis stations. CMS Ex. 1, at 41-42. These insufficiencies, the SOD concluded, "posed a safety risk to staff, visitors, and patients (a universe of 87)." Id. at 41.

42 C.F.R. § 405.2140(a)(2)

Subsection 405.2140(a)(2) of the building and equipment standard requires, among other things, that "[a]ll electrical and other equipment used in the facility [be] maintained free of defects which could be a potential hazard to patients and personnel." The SOD stated that Moreno Valley did not meet this standard because electrical wires and cables supporting the patient dialysis stations were at risk of coming into contact with water and other liquids. CMS Ex. 1, at 43. According to surveyor observations recorded in the SOD, cables, wiring, water hoses and drainage pipes were located within the cabinets behind the patient dialysis stations and "[t]here were multiple areas within the cabinets and in close proximity to the cables and wiring, in which water was leaking." Id. Furthermore, the SOD stated, "[s]ome cabinets appeared wet, and/or had white, brown, and black mold-type staining that showed signs of previous water exposure." Id.

42 C.F.R. § 405.2140(a)(3)

Under subsection 405.2140(a)(3), "[t]he areas used by patients [must be] maintained in good repair and kept free of hazards such as those created by damaged or defective parts of the building." The SOD stated that Moreno Valley's failure to meet this requirement posed immediate jeopardy. According to the SOD, the immediate jeopardy was due to Moreno Valley's failures to: "ensure that the drainage system . . . was constructed and maintained to prevent back-up and overflow of the used dialysate solution" causing "mold and water damage which had the potential for causing fungal infections and respiratory problems;" "ensure that a product water hose . . . was intact and not leaking; and "ensure that tools (pliers), were available to disconnect a tight connection, which delayed a patient's (Patient 3) dialysis treatment for approximately one hour." CMS Ex. 1, at 44.

The findings in the SOD on which CMS relied to support the allegation of noncompliance with subsection 405.2140(a)(3) included the same two groups of findings cited in support of the cited violation of the requirement codified in the lead-in language of section 410.2140(a). Id. at 44-47. In addition, the SOD documented a surveyor interview with a patient's family member, who allegedly stated that about two months before the survey, the water connection to a dialysis machine was so "tightly connected to the wall [that] staff were unable to manually disconnect it." Id. at 47. According to the family member, Moreno Valley staff had stated that the facility's tools had been stolen and the facility did not have pliers to disconnect the water, preventing the patient from receiving dialysis treatment. The SOD stated that the family member reported to the surveyor that "he walked to another business near the dialysis center and borrowed the tools necessary to disconnect the water," and that the patient's treatment was delayed an hour. Id.

42 C.F.R. § 405.2140(a)(5)

The building and equipment requirements at subsection 405.2140(a)(5) incorporate by reference dialysis system water quality monitoring, bacteriology and chemical standards developed by the Association for the Advancement of Medical Instrumentation (AAMI). According to the SOD, Moreno Valley did not meet the AAMI standards because it failed to: "ensure monitoring of bacteria and endotoxin levels in the water by retesting after elevated levels [were] found;" ensure "that water samples were taken at the AAMI . . . recommended locations and within the recommended times;" have a "reverse osmosis tank [that] was cone

shaped with the drainage valve at the lowest point of the tank to ensure complete drainage of the storage water for disinfection;" ensure that "dead spaces in the water loop (where water does not constantly flow) were minimized or removed and that the minimum water velocity of 3 feet per second was maintained;" ensure "that all staff who were responsible for operation of the water treatment system were trained . . . and that periodic competencies were performed to verify the technician's ability to perform . . . his duties"; and "ensure that the policies and procedures for the cleaning and disinfection of the water treatment system [could be] followed with the available supplies." Id. at 48-49; 55-56.

To support the survey findings of noncompliance with the water quality requirements, the SOD stated that the facility's machine culture logs showed that on April 6, 2007, sixteen dialysis machines had elevated bacterial levels and the reverse osmosis (R/O) tank had an elevated level of "potentially toxic" bacterial endotoxins, but the machines and R/O tank were not retested until April 23, 2007. Id. at 49-51, 56-58. Further, the logs "revealed that the bicarbonate storage tank had not been cultured" for the month of May 2007 and the RO storage tank was not cultured for the month of June 2007, contrary to the AAMI recommended guideline that testing should be "performed at least monthly." Id.

The SOD also stated that under AAMI standards, water storage tanks "should have a conical or bowl shaped base and . . . should drain from the lowest point of the base." Id. at 52, 60. The SOD stated that Moreno Valley's product water tank "was flat on the bottom," and that "[t]he lowest point for drainage was approximately one inch from the bottom of the tank." Id. at 52, 59. According to the SOD, the facility's bio-medical technician told the surveyor that the last inch of water [could] not be drained, that the facility needed to get a new tank, and that "the inability to completely drain the tank for disinfection posed the risk for biofilm (a substance that bacteria can reside in) and disinfection chemicals to remain in the product water." Id.

The SOD also stated that: the construction of the pipes delivering product water to numerous patient dialysis stations was inconsistent with AAMI "strategies for bacterial control" because in numerous places the layout created significant "dead space;" the biomedical technician could not confirm the water flow rate in the system; there was insufficient documentation to determine whether the dialysis assistant had been adequately trained and assessed; facility policies and procedures for the

water treatment system stated that formaldehyde should be used, but there was no formaldehyde available in the facility; and there was no documentation reflecting the timing or taking of water cultures. Id. at 52-55, 60.

42 C.F.R. § 405.2140(b)

The lead-in language of the "favorable environment for patients" standard at section 405.2140(b) requires the ESRD supplier to be "maintained and equipped to provide a functional, sanitary and comfortable environment" To support the survey findings that Moreno Valley failed to meet this requirement, the SOD set forth the following findings: The facility's floors were dirty; there was "dust and grime . . . around patient dialysis chairs and machines, as well as in areas of the tile grout;" the ladies' restroom "had dried fecal matter on the toilet seat;" the water treatment room "had dust and debris on the floor and on water storage containers;" "a mop bucket and two mops were stored in the water treatment room next to the sink where dialysate mixing jugs are rinsed and filled with treated water;" the "housekeeper . . . stated that she stores her mops in the water treatment room because there is no housekeeping closet;" according to the biomedical technician, "the water treatment room is considered a clean area;" the cleaning bucket and supplies, including two toilet brushes, were stored underneath the sink in the staff break room; the housekeeper was observed using paper towels and water to clean "sink areas, charts and miscellaneous counters and stated that she did "not use the cleaning supplies while the patients are in the facility because of the smell of the 'Clorox';" the housekeeper stated that there were "no facility policies or procedures regarding how she cleans the facility;" and review of the housekeeper's personnel file "revealed that she did not have any competencies or training regarding how to clean the dialysis unit." Id. at 61-63.

42 C.F.R. § 405.2140(b)(1)

Under subsection 405.2140(b)(1), an ESRD facility must have--

written policies and procedures in effect for preventing and controlling hepatitis and other infections. These policies include, but are not limited to . . . housekeeping, handling and disinfection of waste and contaminants, and sterilization and disinfection. . . .

To support the conclusion that this requirement was not met, the SOD restated findings documented to show the facility's noncompliance with the lead-in language of section 405.2140(b). Id. at 65-66. In addition, the SOD listed the following surveyor observations and alleged employee statements: over one-third of the lid to the bicarbonate mixing/storage tank had been cut out, leaving the bicarbonate solution "open to air;" this tank "was located immediately under multiple pipes and open framing that were visibl[y] dirty and contained debris that could fall directly into the uncovered tank;" the "roll-up type door next to the tank had openings [to] the outside of the building in which insects and dust could enter the area;" under AAMI standards, "bicarbonate mixing tanks should have a tight fitting lid" because "bicarbonate concentrate . . . has been shown to support bacterial growth;" the biomedical technician stated that the cover was "misplaced;" the dialysis assistant stated that the second daily batch of bicarbonate is left in "the opened storage tank for approximately 9 hours;" and "the recommended storage time for uncovered bicarbonate mixtures is three to four hours." Id. at 63-65.

The SOD further included the surveyor's observations that: the housekeeper touched items on the floor and biohazard waste container with gloves on, and then "wiped counters and touched charts without washing her hands or changing her gloves;" one patient care technician went "to two different patient dialysis stations without changing his gloves;" another patient care technician "removed her gloves, touched the biohazard container lid, [then went] to a patient dialysis station in which she touched the dialysis machine, television, and the patient without washing her hands or putting on gloves." According to the SOD, the personnel files "revealed that none of [these three employees] had training in infection control and bloodborne pathogens." Id. at 66-67.

42 C.F.R. § 405.2140(d)(3)

Subsection 405.2140(d)(3) of the emergency preparedness standard requires the facility to have "available at all times on the premises a fully equipped emergency tray, including . . . medical supplies, and equipment" The SOD stated that the standard was not met because Moreno Valley did not "ensure that oxygen was immediately available in case of an emergency" Id. at 67. To support this conclusion, the SOD documented the surveyor's observation that "there were three portable oxygen tanks being stored in the storage room," and "all three were empty." Id. According to the SOD, a patient care technician "confirmed that the three tanks were the only three available in

the facility and that they needed to be refilled across the street at the warehouse." Id. at 68.

42 C.F.R. § 405.2140(d)(4)

Under subsection 405.2140(d)(4) of the emergency preparedness standard, staff must be "familiar with the use of all dialysis equipment and procedures to handle medical emergencies." According to the SOD, the standard was not met as evidenced by staff failure "to ensure that patients had access to the clamp and cut kits," which are "used by the patient for immediate disconnection from the dialysis machine in the event of an emergency and possible evacuation." Specifically, the SOD stated that the surveyor observed that seven patients being dialyzed did not have access to their clamp and cut kits because the kits were placed out of the patients' reach, "on the side of the dialysis machine that was opposite the patient (approximately 4 feet away)." Id. at 68-69.

42 C.F.R. § 405.2140(d)(5)

The requirement at subsection 405.2140(d)(5) provides that patients should be "trained to handle medical and nonmedical emergencies," and that they "must be fully informed regarding what to do, where to go, and whom to contact if a medical or nonmedical emergency occurs." The SOD stated that the standard was not met, as evidenced by statements of several patients that either the facility had not trained them how to respond to emergencies at home, such as bleeding from their dialysis access sites, or they had not been trained to use the clamp and cut kits. The SOD also cited the lack of patient access to clamp and cut kits to support this deficiency finding.

B. Moreno Valley's Submissions to the ALJ and the Board

Moreno Valley's October 4, 2007 request for an ALJ hearing enumerated ten grounds for the appeal, of which the following related to CMS's allegations of noncompliance with the physical environment condition:

4. Allegations that the bathrooms were not clean while in reality we are one in a few of [the] dialysis clinics that has a full-time cleaning staff employee. This is not a requirement but we also do not expect the cleaning person to clean the bathrooms after each patient use, unless so notified.

5. Allegations that the floors have grim[e] while we have a full-time cleaning staff employee that cleans the floor on a daily basis and with approximately 40 people walking on the ceramic floor with shoes on that carry dust from the streets it is not expected that the floor would remain spotless, free from dust all the time regardless.

* * * *

The Department of Health was aware in th[eir] original inspection that the water storage tank was installed more than 10 years ago.

* * * *

9. Concerning allegations about the water treatment system, bicarbonate mixture tanks. No specific reference[s] were ever made by either The Department of Health or CMS that old equipment had to be replaced to current standards by any particular date. Regardless, we were proceeding with replacement of new tanks for the R.O. system and bicarbonate system. If asked we would have mentioned the date of completion time which was September 30, 2007.

10. "All of the paneling has been replaced"

Moreno Valley Request for Review of CMS Determination, October 4, 2007.

In its response to CMS's motion for summary judgment, Moreno Valley made these allegations with respect to the physical environment condition:

1. Each station was equipped with cut & clamp kits. The staff and patients were fully educated on how to use the kit[s] in case of an emergency disaster.

* * * *

3. All patients have been trained in what to do in case of emergency at home if their access site was to start bleeding. It is standard procedure each time the patient is removed from the dialysis machine (see attached statement from patient noted by the investigator [pursuant to the facility's plan of correction]).

4. The contracted biomedical technician used expired supplies for a water culture and did not report the error immediately to their immediate supervisor These were false positive results due to the above mistake and had no effect on any patients.

Moreno Valley Response to CMS Motion for Summary Judgment, January 14, 2008.

In Moreno Valley's request for review of the ALJ Decision, the facility's President argued that more than \$700,000 had been spent to renovate the dialysis unit, which included: contracting for a sprinkler system; hiring an architect; and installing a new R.O water system, new piping, water tanks, cabinets, ceramic tile and lighting fixtures. Moreno Valley Request for Review of ALJ Decision, April 7, 2008. The President stated that "[t]he cleanliness of the unit and unit bathrooms exceed any requirements of the regulations," and repeated the contention that the facility had a full-time cleaning person. Id. Moreno Valley argued that it was unreasonable to expect the facility to inspect restrooms after each patient's use and to clean the floors "follow[ing] behind each and every patient or employee." Id. To require the facility to meet such standards, Moreno Valley argued, constitutes "prejudicial harassment." Id.

In Moreno Valley's May 7, 2008 submission to the Board, the facility's President argued that "a new R.O. system" had been "in place since 2006," that chemical analyses and water cultures were timely taken, and that the cultures were always within normal limits, with the exception of false positive results associated with "the wrong testing tubes." Moreno Valley Reply, May 7, 2008, at 1. The facility submitted logs and laboratory reports to support this contention. P. Exs. 1-2. Moreno Valley also contended that "infection control has been in place all along" and that infection problems have never arisen. Moreno Valley Reply at 1. The facility submitted copies of written patient

care procedures for infection control and isolation techniques for patients with Hepatitis B. P. Ex. 3. Moreno Valley further averred that oxygen was "available at all times" and that a survey finding "than an oxygen tank may be empty . . . does not mean none were available." Moreno Valley Reply at 1. Moreno Valley additionally argued that patients and staff were adequately trained and prepared for emergencies. To support this contention, the facility submitted copies of signed patient instructions on emergency evacuation procedures (including "clamp and cut" procedures) and signed acknowledgments of receipt of such instructions, the majority of which were dated after July 2007. P. Ex. 4.

C. The undisputed findings support summary judgment.

As noted above, the ALJ concluded that Moreno Valley did not directly dispute CMS's allegations of noncompliance with the physical environment condition. Moreno Valley's response to CMS's motion for summary judgment, the ALJ found, did not "allege or offer any facts showing that it complied with [the condition]." ALJ Decision at 4-5. Further, the ALJ concluded, the facility's hearing request did "not explicitly address the allegations of noncompliance with 42 C.F.R. § 405.2140." Id. at 5. The ALJ stated that Moreno Valley's contentions about employing a cleaning person and the heavy use of the facility "simply avoid[ed] answering the question of whether [Moreno Valley] actually maintained clean bathrooms" and provided "an excuse for not complying with regulatory requirements." Id. The ALJ stated that Moreno Valley made no assertions to contest CMS's findings of noncompliance with the emergency preparedness requirements. Id. at 6. Additionally, the ALJ concluded, Moreno Valley's assertions involving the replacement of its water treatment systems were non-responsive to CMS's allegations of noncompliance with the water quality standards and admitted that the replacement of outdated equipment would not be completed until after the survey. Id.

We conclude, as did the ALJ, that Moreno Valley's replacement of outdated equipment and facility renovations after the date of the survey are irrelevant to the question whether CMS's termination action should be upheld. It is well settled that "[t]he dispositive date for assessing whether a facility is out of compliance is the date of the survey from which its termination resulted" and that "compliance efforts by the facility after the date of the survey . . . have no bearing on whether [CMS's] termination determination was correct." Hillman Rehabilitation Center, DAB No. 1611, n.19 (1997), aff'd, Hillman Rehabilitation Ctr. v. U.S. Dep't of Health & Human Servs., No. 98-3789 (GEB)

(D.N.J. May 13, 1999); Carmel Convalescent Hospital, DAB No. 1584, at 12 (1996). Thus, Moreno Valley's contentions below and on appeal to the Board that CMS's termination action should be reversed because the facility completed extensive and costly renovations after the survey are unavailing.

Further, we agree with the ALJ that Moreno Valley's assertions that the facility employed a full-time employee to clean the dialysis center, that numerous people entered and used the facility daily, and that staff should not have been expected to clean the restrooms after each use would not, even if true, satisfy the requirement that the facility actually be "maintained [as a] sanitary, and comfortable environment," as required under the standard at 42 C.F.R. § 405.2140(b)(emphasis added). Indeed, analyzing a factually analogous argument, the Sixth Circuit Court of Appeals concluded that a provider's "evidence of cleaning schedules, procedures, and duties in an attempt to demonstrate that the facility [was] clean, safe, and well maintained . . . established only that [the provider] failed in the execution of its procedures, because the surveyors' observations showed that the facility was noncompliant." Crestview Parke Care Ctr. v. Thompson, 373 F.3d at 751, *rev'g on other grounds Crestview Parke Care Center*, DAB No. 1836 (2006) (a provider's contention that the facility may be observed as unclean at any time because it is constantly in use does not rebut evidence of noncompliance amassed during the survey). As in *Crestview*, the surveyors' uncontested observations of filthy conditions were too widespread and serious to be consistent with any effectively implemented cleaning and sanitation system.

We disagree with the ALJ, however, that Moreno Valley's other contentions wholly failed to address whether the facility complied with the requirements of the physical environment condition. In particular, Moreno Valley's response to CMS's motion for summary judgment, written by the facility's President, expressly disputed the survey allegations that patients and staff were not adequately trained in emergency preparedness and that the clamp and cut kits were unavailable to the patients. Moreover, Moreno Valley's assertion that positive water culture results were due to a contracted employee's mistake in using expired supplies raised an issue of fact with respect to the facility's compliance with the water quality requirements of subsection 405.2140(a)(5).

Similarly, Moreno Valley's allegations on appeal to the Board and its proffers of evidence raised several relevant factual disputes relating to some of the requirements of section 405.2140. Those issues of fact involved Moreno Valley's contentions that: the

cleanliness of the unit and unit bathrooms had exceeded the requirements of the favorable environment standard at section 405.2140(b); the facility performed chemical analyses and water cultures as frequently as called for under AAMI water quality standards pursuant to the building and equipment requirements at subsection 405.2140(a)(5); the facility had written patient care policies to prevent and control hepatitis and other infections, as required under the favorable environment standard at subsection 405.2140(b)(1); and the facility had available oxygen and patient-accessible clamp and cut kits for emergencies, and it had educated patients about emergency procedures, as required under subsections 405.2140(b)(2) and 405.2140(d).

Based on its submissions below and on appeal to the Board, we therefore conclude that Moreno Valley did raise a number of issues of fact relating to the facility's compliance with several requirements of the physical environment condition. These issues of fact, however, were immaterial since the survey findings that Moreno Valley did not contest independently establish the facility's noncompliance with the physical environment condition. That is, even viewing Moreno Valley's submissions in the light most favorable to the facility, construing the facility's allegations of compliance as proffers of testimony that the facility President or another witness would corroborate at a hearing, and assuming the allegations to be true, they would not affect the outcome of this case since the numerous, serious survey findings of fact that the facility did not rebut constitute prima facie evidence that Moreno Valley failed to meet the condition for coverage at 42 C.F.R. § 405.2140.

As set forth above, a supplier fails to meet a condition for coverage at the "condition level" when its "deficiencies are of such character as to substantially limit the . . . supplier's capacity to furnish adequate care or which adversely affect the health and safety of patients." 42 C.F.R. § 488.24(b). In this case, the survey findings of noncompliance that Moreno Valley did not contest were of such character. Most notably, Moreno Valley did not contest the SOD's findings of noncompliance under the lead-in language of section 405.2140(a) and under subsection 405.2140(a)(3), which were documented to have posed immediate jeopardy to facility patients at the time of the survey. Those findings, detailed above, established that the drainage system failed to prevent back-up and overflow of used dialysate solution, a leaking hose was inadequately repaired, there was significant mold and water damage in multiple areas of the unit, and the facility lacked the necessary tools to timely deliver dialysis services to patients. Moreover, Moreno Valley did not contest that at the time of the survey, electrical wires and

cables in the dialysis unit were at risk of coming into contact with water and other liquids, establishing noncompliance under subsection 405.2140(a)(2). The facility also did not contest the survey findings of noncompliance under subsection 405.2140(a)(1), that the fire evacuation plans were too small and difficult to understand. Nor did Moreno Valley dispute that: the construction of the product water pipes was inconsistent with AAMI bacterial control standards (42 C.F.R. § 405.2140(a)(5)); there was no formaldehyde in the facility even though it was required for the water treatment system (42 C.F.R. § 405.2140(a)(5)); there were no written facility policies on housekeeping, housekeeping supplies were stored in the water treatment and staff break rooms, and housekeeping staff had no training in, and did not follow, infection control procedures. (42 C.F.R. §§ 405.2140(b), 405.2140(b)(1)).

In sum, the uncontested findings summarized in the SOD amply establish that at the time of the July 2007 survey, the physical environment of the dialysis unit limited Moreno Valley's capacity to furnish safe and adequate care and adversely affected the safety of its patients. The SOD documented that the defective equipment, mold, fungus and water damage were so serious as to pose the potential for fungal infections and respiratory complications in the facility's immuno-compromised patients. The facility's lack of tools created an inability to deliver timely, adequate care. Further, the possibility that electrical wires and cables in the unit would come into contact with water and other liquids posed serious, inherent safety risks to patients as well as employees. The facility's insufficient fire evacuation plans, construction of product water pipes, lack of formaldehyde and housekeeping practices lend further support to the conclusion that the care being provided to patients at the time of the survey was inadequate and that the facility was unsafe.

Accordingly, we uphold the ALJ's finding that undisputed material facts support the conclusion that Moreno Valley did not meet the physical environment condition for coverage at 42 C.F.R. § 405.2140.

3. CMS's determination to terminate coverage of the services furnished by Moreno Valley is authorized under 42 C.F.R. § 405.2180. FFCL 3.

In its request for an ALJ hearing, Moreno Valley stated that if the State agency "felt that [the facility was] endangering the life of any patient, as they are falsely alleging, rather than waiting from August 7, 2007 [until] September 1, 2007, the unit should have been suspended." Moreno Valley Request for Review of

CMS Determination, October 4, 2007, at 2. Moreno Valley added that, as shown by its ESRD network report and an inspection by Kaiser Permanente, copies of which were attached to the request for review, "[n]o patients suffered." Id.

Section 405.2180(a) of the regulations states:

Except as provided in § 405.2181, failure of a supplier of ESRD services to meet one or more of the conditions for coverage set forth in this subpart U will result in termination of Medicare coverage of the services furnished by that supplier.

Section 405.2181 provides, in turn, that CMS may impose alternative sanctions when it finds that a supplier has failed to "participate in the activities and pursue the goals of [its] ESRD network," and "[t]his failure does not jeopardize patient health and safety."

We uphold the ALJ's conclusion that CMS was authorized to terminate Medicare coverage of, and payment for, the services furnished by Moreno Valley because the facility "failed to comply with at least one condition of participation as an ESRD supplier." ALJ Decision at 7. The mandatory, plain language of section 405.2180(a) compels the termination of Medicare coverage of a supplier's services where the supplier fails to meet a condition for coverage other than the condition involving supplier network participation (42 C.F.R. § 405.2134). No exception is made where a supplier's failure to meet a condition for coverage did not result in actual harm to a patient or patients.

In this case, Moreno Valley failed to meet the condition for coverage at section 405.2140 of the regulations. Accordingly, CMS's determination to terminate coverage for the services furnished by Moreno Valley must be upheld. Furthermore, since the facility's failure to comply with the physical environment condition alone is sufficient to support CMS's termination action, it is unnecessary to address CMS's allegations of the facility's noncompliance with the conditions at 42 C.F.R. §§ 405.2136 and 405.2161.

Conclusion

For the foregoing reasons, we uphold the ALJ Decision entering summary judgment against Moreno Valley for failure to meet the condition for coverage at 42 C.F.R. § 405.2140 (physical environment) and sustaining CMS's determination pursuant to 42 C.F.R. §§ 405.2180(a) to terminate Medicare coverage for the services furnished by Moreno Valley effective at the close of business on August 31, 2007.

_____/s/
Stephen M. Godek

_____/s/
Constance B. Tobias

_____/s/
Leslie A. Sussan
Presiding Board Member